

#### REMARKS

This paper is filed in Response to the Office Action mailed September 14, 2010. Claims 1 to 20 are pending and under consideration. By this Response, claim 4 has been cancelled without prejudice, and new claims 21 to 23 have been added. Accordingly, upon entry of this Response, claims 1 to 23 are under consideration.

#### Regarding the Claim Amendments

The claims have been amended to address various informalities, including the grounds for the objections and the rejection under 35 U.S.C. §112, second paragraph, or are supported throughout the specification. The amendment to claim 19 is supported, for example, at the paragraph bridging pages 10-11. Accordingly, as the amendments to the claims were made to address formalities or are supported by the specification, no new matter has been added and entry thereof is respectfully requested.

#### Regarding New Claims 21 to 23

Claims 21 to 23 are supported throughout the specification. In particular, claims 21 and 22 are supported by originally filed claims 4 and 5. Claim 23 is supported, for example, by originally filed claim 7, and at page 8, lines 7-10. Accordingly, as claims 21 to 23 are supported by the specification, no new matter has been added and entry thereof is respectfully requested.

#### Regarding the Claim Objections

The claims have been objected to for various informalities, as set forth in the Office Action at pages 2-5.

The claims have been amended to conform to the Examiner's suggested remedial measures, as outlined in the Office Action, except as set forth below.

In particular, claim 4 has been cancelled and identical new claim 22 added. Claim 22 depends from claim 21, which recites "essential protein." Accordingly, there is adequate antecedent basis for "essential protein" in claim 22.

Claim 2 has been amended to delete reference to "coding sequence" which is believed to be the cause of confusion. Amended claim 2 now recites that the origin of replication "is" from one of SSV1, SSV2, pSSVx or pRN plasmids.

Claim 11 has not been amended since the claim recites “a reporter protein,” not “a reporter proteins.” Thus, the term is grammatically correct.

Claim 17 has not been amended even if the term “a (poly)peptide” lacks consistency. In this regard, the term (poly)peptide is grammatically correct and clear and definite, and the meaning of claim 17 is also clear and definite. Accordingly, Applicants submit that there is no need to amend claim 17.

In view of the foregoing amendments and remarks, the grounds for objection are moot. Accordingly, Applicants respectfully request that the objections be withdrawn.

I. REJECTIONS UNDER 35 U.S.C. §112, SECOND PARAGRAPH

The rejection of claims 6 and 19 under 35 U.S.C. §112, second paragraph, as allegedly indefinite is respectfully traversed. The ground for rejection is set forth in the Office Action, pages 6-7.

Claim 6 has been amended to clarify that “a translation initiation site” or “a promoter” are a further limitation of the claim. Furthermore, even if there is no gene of interest specified in claim 1, there can still be a “translation initiation site” or “a promoter,” since such sequences can be positioned upstream of a triplet codon of a gene of interest encoding the first amino acid residue. Accordingly, as such sequences can exist independent of a gene of interest, there is no requirement that a gene of interest be present.

Claim 19 has been amended to no longer recite a use, and to properly depend from claim 1. Amended claim 19 also recites that the gene of interest is transcribed into an RNA or antisense RNA, which one of skill in the art would know could be used to reduce or silence gene expression. Accordingly, the grounds for rejection of claim 19 are moot.

In view of the amendments and foregoing remarks, claims 6 and 19 are clear and definite. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112, second paragraph, be withdrawn.

II. REJECTION UNDER 35 U.S.C. §101

The rejection of claims 1 to 4 under 35 U.S.C. §101 as allegedly directed to non-statutory subject matter is respectfully traversed. The ground for rejection is set forth in the Office Action, pages 7-9.

Claims 1 to 4 recite expression vectors which can include elements of the vectors of SSV1, SSV2 and SSVx, but are not the vectors of SSV1, SSV2 and SSVx that occur naturally in Sulfolobus. In this regard, Applicants note that a careful reading of the language in the specification relied upon by the Examiner (noted as paragraph 9, which is at page 3, lines 23-24 of the specification) does disclose that SSV1 and SSV2 refer to types 1 and 2 viruses of Sulfolobus shibatae, namely....“a circular double stranded DNA virus adapted to Sulfolobus.” (Page 3, lines 23-24, Emphasis added). Consistent with the specification and that SSV1 and SSV2 are viruses, Stedman et al. (2003, previously submitted as reference LR on PTO Form 1449) indicates that SSV1 and SSV2 are viruses found in Sulfolobus. Thus, in view of the specification and knowledge in the art one of skill in the art would know that SSV1 and SSV2 refer to viruses, and not Sulfolobus proteins or nucleic acid sequences.

Applicants also note the paragraph bridging pages 6 and 7 in the specification relied upon by the Examiner (noted as paragraph 14 in the Action), but respectfully point out that this description relates to genes and other sequences important for packaging of the pSSVx plasmid into viral particles, not gene(s) encoding an essential protein of sulfolobus. In further support of Applicants' position, the specification discloses that “....SSVx is propagated with the help of a complete virus SSV1 or SSV2.” (Page 10, lines 16-18, Emphasis added). Accordingly, the description section relied upon does not mean that expression vectors consist solely of SSV1 or SSV2 viral sequences.

To provide additional explanation and to assist with the Examiner's understanding of the invention, but without limiting the claims, the specification discloses that “The vector of the present invention allows to successfully and with high efficiency transform Sulfolobus cells, which are a model organism for hyperthermophilic Crenarchaeots. The combination with viral components and a virus-based mode of DNA transfer permits to reach cell, after the initial transformation event, by a process of infection, thereby resulting in a dramatically increased efficiency of transformation.” (Paragraph bridging pages 5-6, Emphasis added) Thus, in view of this explanation in the specification the expression vectors are a combination of sulfolobus and viral components, not just viral components.

As to particular elements which are of *Sulfolobus* origin, Applicants respectfully point out that claim 1(c) recites “one or more selectable marker gene(s) encoding an essential protein of sulfolobus.” [Emphasis added.] An essential protein of *sulfolobus* is necessary for and originates from *sulfolobus*, but is not a viral protein from SSV1 or SSV2 virus that infects *sulfolobus*. The specification description is consistent with an essential protein of *sulfolobus* meaning a *sulfolobus* protein, not an SSV1 or SSV2 viral protein, namely, that “the selectable marker gene of the expression vector encodes an essential protein of *Sulfolobus*,” that essential genes include “a gene of the de novo nucleotide anabolism, a gene of amino acid biosynthesis or a gene conferring antibiotic resistance,” and more particularly, “orotidine-5'-monophosphatase pyrophosphorlyase and orotidine-5'-monophosphatase decarboxylase (pyrEF) as selectable marker genes.” (paragraph bridging pages 7 and 8) In addition, the specification discloses a working embodiment with “the *Sulfolobus* selection marker pyrEF.” (Example 5, page 19, line 5). Accordingly, in view of the specification the recitation of “one or more selectable marker gene(s) encoding an essential protein of *sulfolobus*” in claim 1(c) would not mean SSV1 or SSV1 viral proteins.

Furthermore, claim 1 has been amended to recite an “isolated or purified” *sulfolobus* expression vector. Consequently, the claims do not encompass non-statutory subject matter.

In sum, as the claims are not directed to naturally occurring SSV1 or SSV2 viruses, nor naturally occurring products, the ground for rejection under 35 U.S.C. §101 must be withdrawn.

### III. REJECTION UNDER 35 U.S.C. §102

The rejection of claims 1 to 4, 6, 8, 9, 11 to 15 and 20 under 35 U.S.C. §102(b) as allegedly anticipated by Stedman et al. (*Genetics* 152:1397 (1999)) is respectfully traversed. The grounds for the rejection is set forth in the Office Action at pages 9-10.

Claims 1 to 4, 6, 8, 9, 11 to 15 and 20 are neither taught nor suggested by Stedman et al. (*Genetics* 152:1397 (1999)). As acknowledged by the Examiner, Stedman et al. at most describe a naturally occurring SSV1 genome, i.e., all genes are viral (Figure 1). Stedman et al. disrupt viral ORFs in order to identify the ORFs required for SSV1 function, a virus capable of infecting *Sulfolobus*, but an organism distinct from *Sulfolobus*. However, Stedman et al. do not disclose an SSV1 expression vector with any non-viral genes, let alone one or more selectable marker gene(s) encoding an essential protein for *Sulfolobus*. Furthermore, Stedman et al. fail to teach or suggest introducing any non-viral genes into

SSV1, let alone a non-viral gene encoding an essential protein for Sulfolobus. Accordingly, as Stedman et al. (Genetics 152:1397 (1999)) fail to teach or suggest any of claims 1 to 4, 6, 8, 9, 11 to 15 and 20, the rejection under 35 U.S.C. §102(b) is improper and must be withdrawn.

**CONCLUSION**

In summary, for the reasons set forth herein, Applicants maintain that the claims clearly and patentably define the invention, respectfully request that the Examiner reconsider the various grounds set forth in the Office Action, and respectfully request the allowance of the claims which are now pending.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's representative can be reached at (858)509-4065.

Please charge any fees associated with the submission of this paper to Deposit Account Number 033975. The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

Respectfully submitted,

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